

§ 820.46 Environmental control.

Where environmental conditions at the manufacturing site could have an adverse effect on a device's fitness for use, these environmental conditions shall be controlled to prevent contamination of the device and to provide proper conditions for each of the operations performed pursuant to § 820.40. Conditions to be considered for control are lighting, ventilation, temperature, humidity, air pressure, filtration, airborne contamination, and other contamination. Any environmental control system shall be periodically inspected to verify that the system is properly functioning. Such inspections shall be documented.

§ 820.56 Cleaning and sanitation.

There shall be adequate written cleaning procedures and schedules to meet manufacturing process specifications. Such procedures shall be provided to appropriate personnel.

(a) *Personnel sanitation.* Washing and toilet facilities shall be clean and adequate. Where special clothing requirements are necessary to assure that a device is fit for its intended use, clean dressing rooms shall be provided for personnel.

(b) *Contamination control.* There shall be procedures designed to prevent contamination of equipment, components, or finished devices by rodenticides, insecticides, fungicides, fumigants, hazardous substances, and other cleaning and sanitizing substances. Such procedures shall be documented.

(c) *Personnel practices.* Where eating, drinking, and smoking by personnel could have an adverse effect on a device's fitness for use, such practices shall be limited to designated areas selected so as to avoid such an adverse effect.

(d) *Sewage and refuse disposal.* Sewage, trash, by-products, chemical effluents, and other refuse shall be disposed of in a timely, safe, and sanitary manner.

Subpart D—Equipment**§ 820.60 Equipment.**

Equipment used in the manufacturing process shall be appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, and cleaning.

(a) *Maintenance schedule.* Where maintenance of equipment is necessary to assure that manufacturing specifications are met, a written schedule for the maintenance, adjustment, and cleaning of equipment shall be developed and adhered to. Such schedule shall be visibly posted on or near each piece of equipment, or be readily available to personnel performing maintenance activities. A written record shall be maintained documenting when scheduled maintenance activities are performed.

(b) *Inspection.* Periodic documented inspections shall be made to assure adherence to applicable equipment maintenance schedules.

(c) *Adjustment.* Any inherent limitations or allowable tolerances shall be visibly posted on or near equipment requiring periodic adjustments, or be readily available to personnel performing these adjustments.

(d) *Manufacturing material.* Manufacturing material, including a cleaning agent, mold-release agent, lubricating oil, or other substance used on or in the manufacturing equipment or the device, shall be subsequently removed from the device or limited to a specified amount that does not adversely affect the device's fitness for use. There shall be written procedures for the use and removal of such manufacturing material. The removal of such manufacturing material shall be documented.

§ 820.61 Measurement equipment.

All production and quality assurance measurement equipment, such as mechanical, automated, or electronic equipment, shall be suitable for its intended purposes and shall be capable of producing valid results. Such equipment shall be routinely calibrated, inspected, and checked according to written procedures. Records documenting these activities shall be maintained. When computers are used as part of an automated production or quality assurance system, the computer software programs shall be validated by adequate and documented testing. All program changes shall be made by a designated individual(s) through a formal approval procedure.

(a) *Calibration.* Calibration procedures shall include specific directions and limits for accuracy and precision. There shall be provisions for remedial action when accuracy and precision limits are not met. Calibration shall be performed by personnel having the necessary education, training, background, and experience.

(b) *Calibration standards.* Where practical, the calibration standards used for production and quality assurance measurement equipment shall be traceable to the national standards of the National Bureau of Standards, Department of Commerce. If national standards are not practical for the parameter being measured, an independent reproducible standard shall be used. If no applicable standard exists, an in-house standard shall be developed and used.

(c) *Calibration records.* The calibration date, the calibrator, and the next calibration date shall be recorded and displayed, or records containing such information shall be readily available for each piece of equipment requiring calibration. A designated individual(s) shall maintain a record of calibration dates and of the individual performing each calibration.